IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

PHILADELPHIA FEDERATION OF TEACHERS HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff, v. ALLERGAN, INC., Defendant.	Case No. JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Philadelphia Federation of Teachers Health & Welfare Fund ("Plaintiff" or "the Fund"), on behalf of itself and all others similarly situated, files this Class Action Complaint against Defendant Allergan, Inc. ("Defendant" or "Allergan"), based upon personal knowledge as to facts pertaining to it and upon information and belief as to all other matters, and alleges as follows:

NATURE OF ACTION

1. For nearly four (4) years, Allergan has maintained an unlawful, illegitimate monopoly in the market for cyclosporine ophthalmic emulsion, a product it sells by the name of Restasis. Until May 2014, Restasis was protected by U.S. Patent No. 5,474,979 (the "'979 Patent" or "Ding I Patent,") which issued in 1995. All told, Allergan has made about $3.3 billion from selling Restasis in the U.S. But when it was faced with the looming expiration of the Ding I Patent and potential competition from generic manufacturers of cyclosporine

ophthalmic emulsion in 2013, Allergan concocted an elaborate, anticompetitive scheme to preserve its monopoly beyond the May 2014 expiration of the Ding I Patent. Under this scheme, Allergan has used the laws and courts of the United States to prevent manufacturers of generic cyclosporine ophthalmic emulsion from entering and competing in the relevant market. In fact, Allergan has gone as far as to fraudulently obtain illegitimate patents and then transfer them to a Native American Tribe in order to avoid having them invalidated. This civil antitrust action arises from that scheme and seeks the recovery of damages on behalf of the Plaintiff and a proposed class of purchasers that bought Allergan's brand of cyclosporine ophthalmic emulsion, Restasis, indirectly from Allergan at supracompetitive prices.

PARTIES

2. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code to provide health benefits to its eligible participants and beneficiaries. Philadelphia Teacher's Fund maintains its principal place of business in Philadelphia, Pennsylvania. It provides health benefits, including prescription drug benefits, to approximately 34,000 beneficiaries and covered spouses and dependents. During the Class Period, Plaintiff purchased and/or provided reimbursement for some or all of the purchase price of Restasis, other than for re-sale, at supracompetitive prices, and has thus been injured.

3. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located in Irvine, California. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the Restasis trademark. Allergan also was the applicant for and holder of each of the six

second wave patents which Allergan has claimed cover Restasis: U.S. Patent No. 8,629,111 (dated Jan. 14, 2014); U.S. Patent No. 8,633,162 (dated Jan. 21, 2014); U.S. Patent No. 8,642,556 (dated Feb. 4, 2014), U.S. Patent No. 8,648,048 (dated Feb. 11, 2014), U.S. Patent No. 8,685,930 (dated Apr. 1, 2014), and US 9,248,191 (dated Feb. 2, 2016). As of September 8, 2017, Allergan purports to have transferred its ownership interests in the second wave patents to the Tribe.

4. All of the actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Allergan's officers, agents, employees, or other representatives while actively engaged in the management of Allergan's affairs within the course and scope of their duties and employment, and/or with Allergan's actual, apparent, and/or ostensible authority.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of the Defendant.

6. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendant's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. § 1 and 2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

7. Venue is proper within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1392(b) and (c), because Defendant transacts business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

THE MARKET FOR GENERIC PHARMACEUTICAL DRUGS

8. Novel, non-obvious pharmaceutical drugs are eligible for patent protection under United States law. These patents provide the patent-holders ("Brand Manufacturers") a limited monopoly for a statutorily-prescribed time period in which only they may manufacture, market, and sell their patented drug. The prices at which these drugs are sold by the patent-holders usually substantially higher than often modest costs of production.

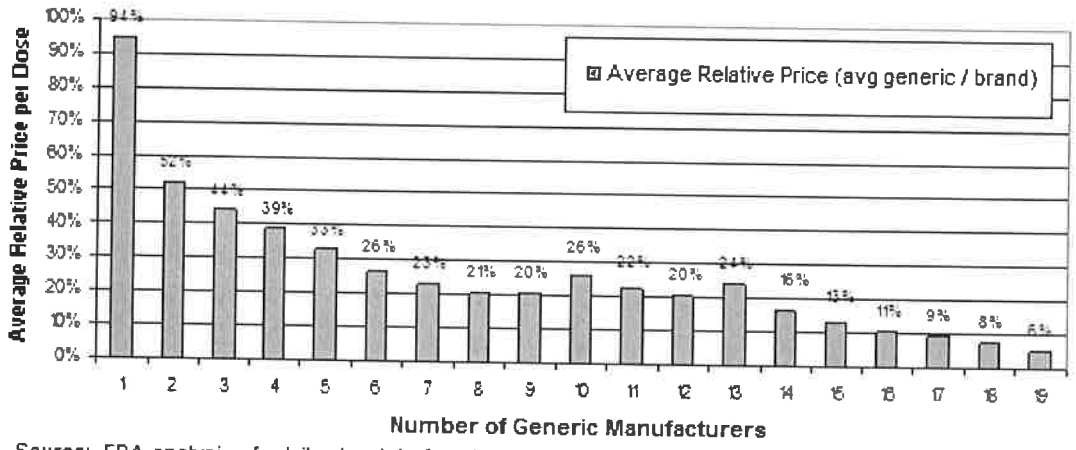
9. Upon the expiration of the statutory time period, competitors may enter the market with lower-cost substitutes colloquially called "generics." Generic drugs contain the same active ingredient as their branded counterparts and are determined by the FDA to be just as safe and effective.

10. Before expiration of its patents, a Brand Manufacturer has a monopoly and captures 100% of sales of its patented drug and can, therefore, charge virtually any price they wish. But when the patent expires and generics become available, the Brand Manufacturer quickly loses market share as consumers flock to less expensive alternatives. Generic drugs are thus generally sold to the public at a far cheaper price than the branded product.

11. Indeed, because generic drugs are commodities that cannot be distinguished on the basis of their active ingredients or their efficacy, the primary basis for competition among generic drug manufacturers is price. When there is only one generic manufacturer, the generic drug is at least 25% less expensive than its brand-name counterpart. When there are

multiple generic manufacturers, this reduction can range anywhere from 50% to 80% (or more), resulting in significant cost savings to both wholesale and retail purchasers. That is because when multiple generic manufacturers enter the market, vigorous competition among them drives the price down to marginal manufacturing costs. As the following chart illustrates, the price of a generic drug naturally tends to decrease as more generic drug manufacturers enter the market:

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

12. The market for generic drugs in the United States is substantial. In fact, approximately 88% of all pharmaceutical prescriptions in the United States are filled with a generic drug. In 2015, generic drug sales in the United States totaled an estimated $74.5 billion. And, importantly, according to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies.

13. Generic competition thus enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

14. Brand Manufacturers, such as Allergan, know full well the negative effect generic drug manufacturers have on their market shares and profit margins. They, therefore, seek ways to extend their monopolies for as long as possible, sometimes through illicit, anticompetitive means.

THE PATENT PROCESS FOR BRANDED DRUGS

15. The patent portfolios of Brand Manufacturers share a fairly common developmental path. The first step usually involves the Brand Manufacturer applying for, and obtaining, a patent that reflects a novel and genuine scientific breakthrough that may later contribute to the success of the drug. This initial patent usually protects the active compound in a prescription drug or a particular pharmaceutical composition and are expectedly quite detailed and extensive.

16. After applying for and obtaining its original patent, a Brand Manufacturer typically continues its research and development efforts with an eye towards obtaining FDA approval and bringing the drug to market. As the Brand Manufacturer's research continues, so, too, do its patent filings. These "second wave" patent filings are often for narrow modifications relating to specific formulations, manufacturing processes, or methods of administration. This renders the original patent filings "prior art" under United States patent law, thus limiting the scope of the "second wave" patents that can be obtained. New patents can usually be obtained only if the Brand Manufacturer demonstrates that the new features of the drug represent non-obvious distinctions over the "prior art," which includes not just the original patent, but also, for example, scholarly research into the subject of the original patent. Additionally, the original patents often disclose methods of using earlier inventions.

Thus, as the number of patent filings grows over time, so does the volume of "prior art" from which the Brand Manufacturer must show non-obvious distinctions.

17. Consequently, since these "second wave" patents are generally more narrow and harder to obtain, they are especially vulnerable to challenges on the grounds that their subject matter is obvious or unoriginal. Moreover, the narrower coverage of these "second wave" patents allows generic manufacturers to design around them more easily, thus preventing the Brand Manufacturer from relying on infringement proceedings to keep generic drugs out of the market.

18. Importantly, patent prosecutions are non-adversarial. Their primary purpose is to promote the public interest by ensuring that issued patents are valid and have been lawfully obtained. To that end, patent applicants are required to disclose to the PTO "all information known . . . to be material to patentability," including with respect to "prior art." *See* 37 C.F.R. § 1.56. This duty of disclosure, candor, and good faith extends to every named inventor on the patent application, every "attorney or agent who prepares or prosecutes the application," and "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id.* § 1.56(c). The PTO is prohibited from granting a patent where fraud by the applicant "was practiced or attempted" or where the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct." *Id.* § 1.56(a).

19. Congress passed the Leahy-Smith America Invents Act ("Leahy-Smith") in 2011 to alleviate the detrimental effect that invalid, unenforceable patents were having on economic growth and innovation. Leahy-Smith created new "*inter partes* review" ("IPR") proceedings which members of the public could use to invalidate improperly-issued patents

more quickly and inexpensively than traditional patent litigation. An IPR provides for patent review by technically-educated members of the PTAB who are deeply familiar with the sciences at issue.

20. IPR proceedings are adversarial in nature. An IPR commences when a party—often an alleged patent infringer—petitions the PTAB to invalidate an existing patent on the grounds that it was obvious or anticipated by "prior art." The PTAB will grant a request for an IPR only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The PTAB must decide the challenge within one (1) year of its commencement.

THE FDA APPROVAL PROCESS FOR GENERIC DRUGS

21. Under the federal Food, Drug, and Cosmetic Act ("FDCA"), a Brand Manufacturer that wishes to bring its breakthrough drug to market must file a New Drug Application ("NDA") with the FDA. Among other things, an NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

22. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA regularly publishes these patents in what is commonly referred to as the "Orange Book," but formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*. If a patent is issued *after* NDA approval, a Branded Manufacturer has 30 days from issuance to list the patent in the Orange Book. The Orange Book puts would-be generic competitors on notice that the Brand Manufacturer has the exclusive right to produce, market, and sell the subject matter of the listed patents.

23. In listing the patents identified by the Brand Manufacturer in the Orange Book, the FDA performs only a ministerial role because it has neither the resources nor the authority to verify the Brand Manufacturer's representations for accuracy. Instead, the FDA assumes the veracity of the Brand Manufacturer's representations regarding the validity and applicability of any patents it submits for Orange Book listing.

24. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, more commonly known as the "Hatch-Waxman Act" (Pub. L. No. 98-417, 98 Stat. 1585). Recognizing the substantial cost savings enjoyed by the consumers of generic drugs, Congress sought to reduce the regulatory hurdles that generic drug manufacturers must clear prior to obtaining FDA approval. Under the Act, generic drug manufacturers may expedite FDA approval by filing an Abbreviated New Drug Application ("ANDA") which demonstrates that its generic product is "pharmaceutically equivalent" and "bioequivalent" to its branded counterpart.

25. Consistent with its goal of expediting the approval and sale of generic drugs, Hatch-Waxman also created a procedural mechanism to quickly resolve patent disputes between Brand Manufacturers and their potential generic competitors. The procedure works like this: once one or more patents are listed in the Orange Book, a generic manufacturer filing an ANDA must certify that the generic drug addressed therein will not infringe any of those patents. It may do so by certifying: (1) that there is no Orange Book patent for the drug that is the subject of its ANDA ("paragraph I certification"); (2) that the applicable Orange Book patent has expired ("paragraph II certification"); (3) if that patent has not expired, that the generic manufacturer will not market its product until it has ("paragraph III

certification"); or (4) that the Orange Book patent is invalid or will not be infringed by the generic manufacturer's product ("paragraph IV certification").

26. The Hatch-Waxman Act permits a Brand Manufacturer to sue the ANDA applicant for patent infringement if it files a paragraph IV certification. If the infringement action against the generic manufacturer is commenced within 45 days of receiving notification of the paragraph IV certification, the FDA will not approve the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until such time, the FDA cannot finally approve the ANDA, although it may grant tentative approval if it determines that, but for the 30-month stay, the ANDA would otherwise be ready for final approval. If the Brand Manufacturer, however, initiates its infringement action more than 45 days after being notified of the paragraph IV certification, the statutory 30-month stay does not apply.

27. Hatch-Waxman also grants the first generic manufacturer to file an ANDA containing a paragraph IV certification (the "First Filer") a 180-day monopoly in the generic market if that manufacturer is successful in challenging the validity of the patent. As a result, later ANDA-filers will not be able to market their own generic products for at least six months after the First Filer's generic product hits the market. During this six-month "exclusivity" period, the First Filer competes only with the Brand Manufacturer and, while it often sells its generic product at a lower price than its branded counterpart, the price would almost always be lower if it were facing vigorous competition from other generic manufacturers.

28. Since Hatch-Waxman's enactment, every state has adopted "substitution laws" permitting, and sometimes requiring, retail pharmacies to substitute generic drugs for their branded equivalents when filling prescriptions, unless the prescribing physician specifically orders otherwise, in writing, on the prescription.

THE CITIZEN PETITION PROCESS UNDER THE FDCA

29. Section 505(j) of the FDCA allows any person to file a petition with the FDA—commonly referred to as a "citizen petition"—requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. Citizen petitions provide individuals the opportunity to express their genuine and well-informed opinions regarding actual or potential FDA action. Typically, these opinions relate to the scientific, medical, or legal issues regarding a product both before and after it has come to market.

30. FDA regulations require the FDA Commissioner to approve or deny each petition, in whole or in part, within 180 days of receipt. The Commissioner also may provide a tentative response with an estimate on a time for a full response. Naturally, the review and response process is time-consuming and a strain on the FDA's limited resources because FDA employees must first research and analyze the relevant scientific, medical, legal, and economic issues implicated by the petition and then coordinate internal agency review and clearance of the response. The FDA generally refrains from approving an ANDA until after it responds to all citizen petitions concerning that ANDA. This has been a longtime practice of the FDA that is well-known throughout the pharmaceutical industry.

31. For more than a decade, the citizen petition process has lent itself to abuse by several Brand Manufacturers who use it as a tactic to delay competition from generic competitors. Often, a Brand Manufacturer's petition raises no legitimate concerns as to the safety or efficacy of generic products. Instead, the petition is used by the Brand Manufacturer to prolong the ANDA approval process, thereby extending its monopoly beyond the expiration of its patent. Indeed, empirical evidence demonstrates that most citizen petitions filed by Brand Manufacturers are on filed just prior to impending FDA approval of an ANDA, even though the petition could have been filed months, or even years, earlier. Generally, the monopoly benefits of delaying generic competition far outweigh the relatively menial cost to the Brand Manufacturer of filing a meritless citizen petition. In some cases, citizen petitions regarding ANDAs have been pending for a year or more, long after the 180-day statutory deadline.

32. The FDA has acknowledged Brand Manufacturer abuse of the citizen petition process. As far back as 2005, the FDA cited "several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try [to] delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

33. Abuse of the citizen petition process partially motivated Congress to pass the FDA Amendments Act of 2007, 21 U.S.C. 355(q) (the "2007 Act"), which added new section 505(q) to the FDCA. This section generally prohibits the FDA from withholding approval of an ANDA during the six-month petition review process. An exception is

provided for instances in which the FDA determines that a delay is necessary to protect the public health. Brand Manufacturers, however, have continued to abuse the process by filing citizen petitions that implicate issues of public health.

34. To this day, the FDA continues to express concern that citizen petitions are being used by Brand Manufacturers for anticompetitive purposes. It noted in a 2012 report to Congress, for example, that "based on the petitions that FDA has seen to date…the agency is concerned that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products." Recent studies on this precise issue support the FDA's concern. One study, for instance, found that many citizen petitions from brand manufacturers "appear to be last-ditch efforts to hold off generic competition," and that between 2011 and 2015, ***the FDA denied 92% of section 505(q) citizen petitions***, which are the type most often used to delay generic entry. *See* Feldman *et al.*, *Empirical Evidence of Drug Pricing Games – A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 70 (2017); Carrier & Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 332-333, Table 4 (2016).

ALLERGAN'S UNLAWFUL MONOPOLISTIC AND ANTICOMPETITIVE CONDUCT WITH RESPECT TO RESTASIS

The FDA Approves Restasis

35. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis. Restasis is a topical eye drop consisting of various components, including the active ingredient cyclosporin A, an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is most commonly used to treat a condition called

"dry eye," which is caused by the failure to produce tears in the normal fashion. Restasis is one of the most widely prescribed drugs in the world; last year, in the United States alone sales of Restasis were nearly $1.5 billion.

36. In 1993, Allergan obtained a license from Sandoz, Inc. to use and further refine the technology of treating "dry eye" with cyclosporine. That technology was protected by U.S. Patent No. 4,839,342 ("the '342 Patent"). The '342 Patent claimed that, by topically administering cyclosporine to the eye, lacrimal gland tearing could be restored. The '342 Patent cited castor oil, among other compounds, as a pharmaceutically acceptable vehicle for topically administering cyclosporine to the eye.

37. Since cyclosporine is not very water-soluble, Allergan had to develop both a hydrophobic vehicle that would dissolve the cyclosporine and an emulsifier that would prevent the castor oil from separating from the water. Allergan obtained two (2) patents for these two inventions, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "the Ding I Patent"), issued in 1995.

38. The Ding I patent contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. The Ding I Patent stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the more preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12. The formulation for Restasis falls within the range of values disclosed and claimed in the Ding I Patent.

39. The second patent obtained by Allergan, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II Patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II Patent disclosed and claimed a method of alleviating dry eye related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

40. After obtaining the Ding I and Ding II Patents, Allergan began clinical trials of various combinations of cyclosporine and castor oil. In the first trial (the "Phase 2 Study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (e.g., 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). In May 2000, the results of the Phase 2 Study were published in a scholarly article authored by Dara Stevenson titled *Efficacy and Safety of Cyclosporine A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose- Ranging, Randomized Trial*, 107 Ophthalmology 967 (May 2000). The study concluded that all tested concentrations significantly improved the symptoms of moderate-to-severe dry eye disease, and mitigated the disease's effects on vision. All tested concentrations were deemed safe and effective in increasing tearing in certain patient groups.

41. Notably, Stevenson concluded that there was no statistically significant difference in the benefits afforded by the 0.05% cyclosporine formulation and the formulations containing higher amounts of cyclosporine. In other words, more did not equal better. The 0.1% cyclosporine formulation, however, "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the most

consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

42. The Phase 3 Study followed Stevenson's advice and focused on the efficacy of the 0.05% and 0.1% formulations. The results were published in an article by Kenneth Sall, et al. entitled *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000) ("Sall Article"). In addition to confirming the Phase 2 results, the Phase 3 Study found that the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, which also produced significant improvements over the patient's baseline. This finding suggested that castor oil was critical to the formulations' success. Further, as the Phase 2 results first suggested, there was no statistically significant different between the efficacy of the 0.05% and the 0.1% formulation.

43. Upon completing the Phase 3 Study, Allergan filed an NDA with the FDA seeking authorization to market the 0.05% cyclosporine product proven safe and effective by the Phase 3 Study. The proposed commercial product—Restasis—would contain all the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil.

44. Allergan's NDA was approved by the FDA in December 2002. Allergan was authorized to market and sell Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-

inflammatory drugs or using punctal plugs." Since its initial marketing in 2003, Restasis has earned Allergan billions of dollars in profit.

Allergan files, and the PTO rejects, numerous additional patent applications with the goal of extending its Restasis monopoly.

45. In the ten-plus years following the FDA's approval of Restasis, Allergan filed numerous patent applications attempting to obtain patents on various combinations of castor oil and cyclosporine, even though the Phase 2 and 3 Studies had already shown no change in efficacy between them. Among others, Allergan filed U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application was based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan later withdrew a number of the claims in the '857 application, and, unsurprisingly, the PTO examiner rejected the remainder, in part, because of their obviousness under the Ding I Patent.

46. In 2007, Allergan amended the '857 application to include a claim to an allegedly unique emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those components in Restasis. Expectedly, the PTO examiner rejected Allergan's amended application. Allergan appealed and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was virtually identical to the '857 application, but added claims regarding new conditions Restasis could effectively treat, including corneal graft rejection.

47. In June 2009, Allergan backtracked its claims in the '857 and '177 application and conceded that the various composition claims therein were obvious under the Ding I

Patent. Allergan conceded, in writing, "that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant" and that "in making this selection (0.05% cyclosporine and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." Allergan admitted that the composition claims advanced by the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal.

48. Notwithstanding the lack of originality in the '857 and '177 applications, Allergan tried once more to add a new claim regarding another composition of cyclosporine and castor oil. As with all the others, the PTO examiner rejected the new composition claim as obvious under Ding I. In April 2011, Allergan abandoned the '857 application. The '177 application, on the other hand, ultimately issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use as treatment for corneal graft rejection.

49. In August 2013, having repeatedly failed to obtain patent protection over its various "new" composition claims, and faced with the May 2014 expiration of Ding I, Allergan filed six (6) additional continuation applications deriving, directly or indirectly, from the '177 application ("2013 Applications"). These six applications were identical with only minor variations, modifying the prior specifications by adding four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine.

50. Not surprisingly, Allergan used the 2013 Applications to backtrack from its earlier concession that various cyclosporine-castor oil combinations were obvious under Ding I. The company now claimed to have a new basis for patentability arising from "unexpected" results showing the '877 and '177 formulations to be especially effective. The PTO again rejected the claims presented by the 2013 Applications as obvious under Ding I.

51. Not taking its defeat lightly, in October 2013, Allergan submitted declarations from two of its scientists which purportedly demonstrated, according to Allergan, that the Restasis formulations reflected in the 2013 applications outperformed other combinations to a "surprising" extent not anticipated by Ding I and other "prior art." Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated surprising test results, namely:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . .. Exhibits E and F also illustrate that the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

52. Upon reviewing Dr. Schiffman's declaration, the PTO examiner reversed course. The examiner deemed the Schiffman declaration "sufficient to overcome the rejection…based on [Ding I]…because…Examiner is persuaded that, unexpectedly, the

claimed formulation…demonstrated an 8-fold increase in relative efficacy…" The examiner permitted patents to issue with respect to all six applications. U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), and 8,685,930 ("the '930 patent") were all issued in 2014. U.S. Patent No. 9,248,191 ("the '191 patent") was later issued in 2016. Collectively, these are the "second wave" patents at issue in this case.

53. As it turns out, the statements and data reflected in Dr. Schiffman's declaration that Allergan told the PTO examiner presented "new and unexpected results" were, in fact, not "new" or "unexpected" at all. Rather, Dr. Schiffman's declaration consisted of statements lifted from the Sall Article published 13 years earlier—the article which reported the results of Allergan's own Restasis Phase 3 Study from the late 1990s. *See* Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 Ophthalmology 631 (April 2000).

54. In addition to not being "new," the 2013 Applications failed to demonstrate unexpected results. As the federal court which invalidated the second wave patents found (*see* Invalidation Decision at 133), Allergan's

> presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent." A federal court invalidating the patents that subsequently issued from these applications later found, "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014." *Allergan, Inc. et al. v. Teva Pharmaceuticals*

> *USA, Inc., et al.*, No. 2:15-cv-01455, ECF No. 523 at 20 (E.D. Tex. Oct. 16, 2017) (hereinafter, "Invalidation Decision").

55. The 2013 Applications sought new patent protection on substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of Ding I. The PTO examiners granted these claims only upon reliance on Schiffman's Declaration and Allergan's false assertions of "new" data and "surprising" results.

56. Allergan's affirmative misrepresentations regarding the novelty of the data in the 2013 Applications were intended to deceive, and did deceive, the PTO into issuing the second wave patents. As one federal court later found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO…and the fact that the examiner concluded that unexpected results had been shown…the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, painted a false picture of the comparative results of the Phase 2 and Phase 3 trials. In ad-dition, that presentation created the misleading perception that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of unexpected results to be entitled to no weight, based as it was on evidence that did not accurately depict the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

57. Allergan's misrepresentations and omissions were material because, had the PTO examiner known that the statements and data in the Schiffman Declaration were lifted from the Sall Article that Allergan was aware of for 13 years, the PTO examiner would have rejected each of the 2013 Applications for the same reasons it had denied every earlier application: the claims presented were all obvious under the Ding I Patent.

Allergan improperly lists its "second wave" patents in the Orange Book with the goal of providing itself a pretext for initiating dilatory, sham infringement litigation against potential generic competitors.

58. The first of the second wave patents to issue was the '111 Patent, issued on January 14, 2014. Allergan immediately listed this patent in the Orange Book. As explained earlier, the listing required any ANDA filer seeking to market generic Restasis to file a certification as to that "new" patent.

59. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, it received at least one ANDA for generic Restasis. Up until the listing of the second wave patents, ANDAs may have been filed with paragraph II and/or III certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014, then just months away. Any paragraph II and/or III certified ANDAs would have been unhindered by any patent or citizen petition, resulting in approval of generic Restasis as early as May 17, 2014. The subsequent competition that would have ensued between Allergan and generic manufacturers would have immediately benefited Plaintiff and the proposed class in by way of lower prices.

60. As a result of Allergan's wrongful listing of the '111 patent in the Orange Book, earlier ANDA filers now had to amend their applications to include paragraph IV certifications with respect to the '111 patent (and, eventually, the other five "second wave" patents). To make matters worse, the Allergan created incredible confusion with its last-minute patent applications and Orange Book listings because the order in which the FDA received any prior ANDA certifications was likely different than the order in which the agency received the paragraph IV certifications, creating uncertainty as to who the "First-Filer" was.

61. By effectively requiring all ANDA applicants to file paragraph IV certifications with respect to the second wave patents, Allergan's wrongful Orange Book listings enabled it to sue for patent infringement which, in turn, triggered the FDA's automatic 30-month stay.

62. Allergan knew when it listed its second wave patents that they were invalid. The goal, however, was to provide Allergan a pretext to initiate sham infringement litigation against ANDA applications as a means of delaying generic competition beyond May 2014.

63. The generic manufacturers that, to date, have filed ANDAs seeking to market generic Restasis include Watson, Teva, Mylan, Akorn, Apotex, Innopharma (Pfizer subsidiary), Famy Care, Twi Pharmaceuticals, and Deva Holding. But for the resource-drain, confusion, and administrative delays experienced by FDA and Restasis ANDA filers resulting from Allergan's improper Orange Book listing and subsequent anticompetitive conduct, some or all of these generic competitors would have been approved and on the market as early as May 2014.

64. The existence of multiple patents in the Orange Book, the filing of complex citizen petitions, and the cost of patent litigation, both separately and in conjunction, can and do deter generic manufacturers from submitting and/or pursuing ANDA's. The process of evaluating and contesting even baseless (but complicated) legal or scientific assertions necessarily increases the time and resources required of everyone involved. Typically, because of its accumulation of monopolistic profits, the only interested party that can afford the costs of such dilatory conduct is the Brand Manufacturer—in this case, Allergan.

Allergan commenced meritless infringement litigation to delay and frustrate competition from generic manufacturers.

65. As Allergan had planned, after it listed its "second wave" patents in the Orange Book, its generic competitors provided paragraph IV certifications. Starting in July 2015, and within weeks of one another, generic manufacturers Apotex, Akorn, Mylan, and Teva each submitted paragraph IV certifications. asserting that the "second wave patents" were either invalid or non-infringed by their generic products. Allergan responded to each of these certifications by filing multiple patent infringement actions, beginning on August 24, 2015. These infringement suits triggered the FDA's automatic 30-month stay of any final ANDA approval.

66. A trial was held in August and, on October 16, 2017, a federal court found Allergan's "second wave" patents invalid as "obvious" in light of "prior art." In its detailed 135-page post-trial "Findings of Fact and Conclusions of Law," the district court found that Allergan had secured the "second wave" patents "by way of a presentation that was more advocacy than science." *See* Invalidation Decision at 133. The court further explained that,

> [w]hile Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [second wave] Restasis patents has barred any direct competition for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.

67. Allergan had conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the second wave patents) were obvious in light of Ding I, and Allergan knew it had obtained the second wave patents only through its

fraudulent misrepresentations to the PTO. Thus, Allergan's patent infringement suits were meritless, dilatory, and vexatious.

68. Rather, the true goal of Allergan's infringement actions was to exploit the Hatch-Waxman Act to delay generic competition. Allergan knew that it would derive a benefit from even the most frivolous patent infringement suits since their filing would trigger the FDA's automatic 30-month stay of generic approval. It is believed, and therefore averred, that each month without generic competition to Restasis generated Allergan $125 million in revenues.

Allergan abused the FDA's citizen petition process to delay and frustrate competition from generic manufacturers.

69. In addition to manipulating and exploiting the Hatch-Waxman Act to serve its anticompetitive ends, Allergan also abused the FDA's citizen petition process to further delay competition from generic Restasis manufacturers.

70. Allergan's petitions related to the FDA's June 2013 non-binding draft guidance giving Restasis ANDA applicants two (2) options to demonstrate the bioequivalence necessary to secure approval. The draft guidance stated that ANDA applicants could demonstrate their products' bioequivalence to Restasis in one of two ways: (1) through in vivo testing (*i.e.*, testing performed on live humans); or (2) through in vitro testing (*i.e.*, a test tube). The latter of these methods is generally preferred among generic manufacturers because it is the cheaper and less time-consuming of the two options. The FDA has also been supportive of this preference given that in vivo testing "may present economic and logistical challenges for ANDA sponsors."

71. In a lengthy comment submitted to the FDA in August 2013, Allergan asserted that no ANDA should be approved solely on the basis of in vitro testing. Allergan requested that the FDA "replace the Draft Guidance with a revised guidance document that explains in vivo comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to" Restasis. Allergan's criticism was parroted in public comments submitted by several doctors who received payments of up to $70,000 from Allergan in 2013 for "consulting" on Restasis.

72. In January 2014, after wrongfully listing the '111 patent in the Orange Book, Allergan continued its dilatory conduct by inundating the FDA with citizen petitions. With an eye towards impeding the FDA's review of any Restasis ANDAs, Allergan filed numerous lengthy and baseless citizen petitions in which it admonished the FDA that "rushing prematurely to approve a proposed generic drug [not supported by in vivo clinical endpoint studies] poses a risk to patient health." As with all their conduct up to that point, Allergan's true goal was to delay the FDA's review of any Restasis ANDAs—a strategy that Allergan openly admitted was a response to "intense competition from generic drug manufacturers."

73. Allergan submitted its first petition on January 15, 2014, which was superseded by another petition filed on February 28, 2014. Among the six (6) requests in the February 2014 petition—each of which required a formal, time-consuming response from the FDA within 180 days—was one which requested that the FDA "make clear that the only way to demonstrate bioequivalence to Restasis is through comparative clinical endpoint studies [i.e., in vivo]," and "refus[e] to accept or approve any [Restasis] ANDA if it does not include

data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence."

74. In its November 20, 2014 response to the February 2014 petition, the FDA informed Allergan that its June 2013 draft guidance was consistent with "the Agency's authority to make bioequivalence determinations on a case-by-case basis using in vivo, in vitro, or both types of data." This authority allowed the FDA "to effectuate several long-standing policies that protect the public health" when approving ANDAs. The FDA then explained in vivo studies of "locally acting, non-systemically absorbed drug products" like Restasis were "usually of limited utility" since the "modest efficacy demonstrated by Restasis" rendered an in vivo study unfeasible or unreliable. The FDA then explicitly denied Allergan's request that it reject ANDAs based on in vitro bioequivalence studies, concluding that "an in vitro study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic Restasis.

75. But Allergan would not be dissuaded from its goal of delaying generic competition. To that end, it submitted a *second* citizen petition on December 23, 2014 which largely repeated the arguments it made in its February 2014 petition. Allergan supplemented the December 2014 petition four times, including in August 16, 2015 when it requested that the FDA convene a committee of outside experts to evaluate the use of in vitro methods for testing the bioequivalence of generic Restasis products and that the FDA refuse to review or approve any ANDAs until that evaluation was completed.

76. Again, the FDA denied Allergan's December 2014 petition and its many supplements, stating in its February 10, 2016 response that the December 2014 petition "repeat[ed] many of the assertions that were at the center of Allergan's previous petition."

The FDA did, however, grant two of Allergan's minor requests, but they did not change the FDA's practice. In the absence of Allergan's meritless petitions, the FDA would have still taken the requested actions.

Allergan unlawfully conspires with the Saint Regis Mohawk Tribe in a shameless and transparent effort to avoid having its "second wave" patents invalidated by the PTAB.

77. In June 2015, Apotex was the first ANDA applicant initiation IPR proceedings with the PTAB relative to the "second wave" patents. Six months later, in December 2015, Allergan entered into a confidential settlement with Apotex just days before the PTAB was set to make a determination. Because the terms of that settlement have not been made public, Plaintiff is presently unable to determine whether it may have included a payment from Allergan to Apotex, which would constitute yet another component in Allergan's unlawful scheme. *See FTC v. Actavis*, 133 S. Ct. 2223 (2013).

78. In December 2016, the PTAB was confronted with a similar challenge to the "second wave" patents initiated by generic manufacturers Mylan and Teva a year earlier. The PTAB concluded there was a reasonable likelihood that each of the "second wave patents" would be invalidated upon further review. As a result, proceedings were instituted against all six of the "second wave" patents.

79. On September 8, 2017, in a desperate attempt to avoid having the "second wave" patents invalidated by the PTAB, Allergan and the Saint Regis Mohawk Tribe ("the Trive") entered into an agreement whereby Allergan would convey ownership of the "second wave patents" to the Tribe and, in return, the Tribe would provide Allergan an exclusive license to use the patents for "all FDA-approved uses in the United States" and promise not to waive the Tribe's sovereign immunity with respect to any legal or administrative action

related to the patents. Under the agreement, Allergan would pay the Tribe $13.75 million, plus an additional $15 million in potential annual royalties. On September 22, 2017, after this unlawful agreement was finalized, Allergan petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on the Tribe's sovereign immunity.

80. The Tribe, for its part, entered the agreement solely for the money. The Tribe, in fact, has gone as far as to publicly disclaim any actual business interest in the pharmaceutical industry. *See* Saint Regis Mohawk Tribe Office of Technology, Research and Patents, *Frequently Asked Questions About New Research and Technology (Patent) Business* at 1, *available at* https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.").

CLASS ACTION ALLEGATIONS

81. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), as representatives of an End Payor Class defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for Restasis and/or its AB-rated generic equivalents in the United States, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End Payor Class"), other than for resale, during the period May 7, 2014 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Restasis or its generic equivalent if they paid or reimbursed some or all of the purchase price.

82. The following persons or entities are excluded from the proposed End-Payor Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Restasis or its AB-rated generic equivalent for purposes of resale or directly from Defendant or its affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. Any "brand loyalist" consumers or third-party payors who purchased Restasis and who did not purchase any AB-rated generic equivalent after such generics became available;

g. Pharmacy benefit managers; and

h. The judges in this case and any members of their immediate families.

83. Members of the End Payor Class are so numerous that joinder is impracticable. Plaintiff believes that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

84. Plaintiff's claims are typical of the claims of the members of the End Payor Class. Plaintiff and all members of the End Payor Class were damaged by the same wrongful conduct of Defendant's, *i.e.*, they paid artificially inflated prices for Restasis and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Restasis due to Defendant's wrongful, anticompetitive conduct.

85. Plaintiff will fairly and adequately protect and represent the interests of the End Payor Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

86. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

87. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendant has acted on grounds generally applicable to the entire End Payor Class, thereby making overcharge damages with respect to the Class as a whole appropriate.

88. Questions of law and fact common to the End Payor Class include, but are not limited to:

a. whether Allergan willfully obtained or maintained monopoly power over Restasis and its generic equivalents;

b. Whether Allergan obtained the second wave patents by fraud;

c. Whether Allergan unlawfully excluded competitors from the market for Restasis and its AB-rated generic equivalents;

d. Whether Allergan unlawfully delayed or prevented generic manufacturers of cyclosporine ophthalmic emulsion from entering the market in the United States;

e. Whether Allergan possessed monopoly power over Restasis;

f. Whether Allergan's agreement with the Tribe violated Section 1 of the Sherman Act;

g. Whether there was any legitimate business justification for the anticompetitive contract between Allergan and the Tribe, and whether the anticompetitive effects of that contract outweigh any reasonable procompetitive benefits or justifications;

h. Whether Allergan and the Tribe conspired to monopolize the Restasis market;

i. Whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

j. Whether the activities of Defendant as alleged herein have substantially affected interstate commerce;

k. Whether, and to what extent, Defendant's conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class; and

l. The quantum of aggregate overcharge damages to the Class.

89. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

90. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

MARKET POWER AND MARKET DEFINITION

91. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate

role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

92. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Restasis, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

93. Allergan and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

94. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of

the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

95. Allergan had the ability to control the price of Restasis and exclude relevant competitors. Direct evidence demonstrates that: (a) generic versions of Restasis would have entered the market much sooner at a much lower price compared to Restasis but for Allergan's anticompetitive conduct; (b) the gross margin on Restasis was at all times at least 60%; and (c) Allergan never lowered the price of Restasis to a competitive level in response to the pricing of other therapeutic alternatives.

96. As a result, Allergan sold Restasis far in excess of marginal costs, far in excess of the competitive price, and enjoyed unusually high profit margins.

97. To the extent that Plaintiff is required to show market power indirectly, Plaintiff alleges that the relevant geographic market is the United States and its territories and possessions. The relevant product market is the market for Restasis and its AB-rated generic equivalents.

98. At all relevant times, Allergan's share of the relevant market was and remains 100%.

99. At all relevant times, Allergan had a monopoly in the market for Restasis and its generic equivalents because it had the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other equivalent products, which it worked to keep from entering the market.

100. Allergan needed to control only Restasis and its generic equivalents, and no other products, in order to maintain the price of the product profitably at supracompetitive

prices. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to profitably maintain supracompetitive prices Restasis.

101. Restasis is not reasonably interchangeable with any products other than its generic equivalents because its attributes are significantly different from other chronic dry eye disease ("DED") treatments. The FDA does not consider Restasis and other DED treatments to be interchangeable.

102. Additionally, even drugs within the same therapeutic class do not constrain the price of Restasis. Artificial tears offer only temporary relief and do not address the underlying causes of DED. Corticosteroids can be effective in treating DED, but they have unwanted side effects. Devices like "punctal plugs," which block the tear ducts and help the eye retain naturally produced tears for longer, also have undesirable side-effects. Patients using cyclosporine are unlikely to switch to these products in sufficient numbers following a small, but significant, increase in the price of cyclosporine. Last year, for example, Shire US, Inc. introduced its rival DED product, Xiidra, which, to date, has not resulted in lower Restasis prices. This confirms Allergan's continued market power in the relevant market.

103. It may be that Allergan is also improperly using its monopoly power in the cyclosporine market to unlawfully restrain Xiidra sales. In a recently filed antitrust complaint, Shire alleges that Allergan has engaged in an "ongoing, overarching, and interconnected scheme to systematically block Shire from competing with Allergan." Compl., *Shire US, Inc. v. Allergan, Inc. et al.*, No. 2:17-cv-07716 (D.N.J. Oct. 2, 2017).

104. Allergan's ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates lack of substitutability between Restasis and other drug products.

105. Restasis does not exhibit significant, positive cross-elasticity of demand with respect to price with any other DED medication. Other various DED treatments may exist, but none exhibit cross price elasticity with Restasis at competitive prices, and therefore do not constrain the price of Restasis to the competitive level. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise and maintain Restasis prices above the competitive level, and therefore those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives, to the extent existent, are not the same as economic alternatives.

106. Functional similarities between Restasis and other DED medications, other than AB-rated generic Restasis equivalents, are insufficient to permit inclusion of those other products in the relevant market because they do not exert sufficient pressure on the price and demand for Restasis and its AB-rated generic equivalents. Stated differently, no other DED medication can capture enough of the market for Restasis to prevent Allergan from maintaining supracompetitive prices.

MARKET EFFECTS AND CLASS DAMAGES

107. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market and begun competing with Allergan as early as May 17, 2014 when the Ding I and related patents expired.

108. Additionally, if Allergan had not defrauded the PTO, (i) the "second wave" patents would never issued, (ii) Allergan could never have used those patents as a veil to commence dilatory sham litigation against potential generic competitors, and (iii) generic manufacturers would have been able to begin marketing generic much sooner.

109. Allergan's anticompetitive conduct had the purpose and effect of unreasonably restraining and injuring competition by creating barriers to market entry for generic Restasis products. Allergan's actions allowed it to maintain its monopoly and exclude competition in the relevant market beyond the date that the Ding I and related patents expired.

110. But for Allergan's illicit conduct as alleged herein, several generic competitors would have been ready, willing, and able to market their generic version of Restasis as early as May 17, 2014.

111. Upon entering the market, generic drugs are often priced significantly lower than their branded counterparts. As a result, the brand drug is quickly substituted by their generic counterparts for most purchases. As more generic manufacturers enter the market, prices for generic drugs predictably plummet even further because of price competition among them. Correspondingly, the brand drug continues to lose even more market share to its generic counterparts.

112. This price competition enables all purchasers of the drug to: (a) purchase generic equivalents at substantially lower prices; (b) purchase lower-priced generic equivalents sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, Brand Manufacturers have a serious financial interest in delaying and impairing generic competition, which causes consumers to continue paying monopoly prices.

113. But for Allergan's anticompetitive conduct in hindering the approval and sale of generic Restasis, indirect purchasers, such as Plaintiff and members of the Class, would have paid less for cyclosporine ophthalmic emulsion by (a) purchasing generic equivalents instead, (b) receiving discounts on their remaining branded Restasis purchases, and/or (c) purchasing Restasis at lower prices sooner.

114. Thus, Allergan's unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

115. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Restasis indirectly from Allergan. Because of Allergan's unlawful anticompetitive conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were substantially higher than the prices Plaintiff and members of the Class would have paid absent Allergan's unlawful conduct as alleged herein, because: (1) the price of brand-name Restasis was artificially inflated by Allergan's unlawful conduct, and (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Restasis sooner.

116. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

EFFECT ON INTERSTATE AND INTRASTATE COMMERCE

117. At all material times, Allergan manufactured, marketed, promoted, distributed, and sold substantial amounts of Restasis in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

118. At all material times, Allergan transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Restasis.

119. In furtherance of its efforts to restrain competition in the relevant market, Allergan employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Allergan's activities were within the flow of and have substantially affected interstate commerce.

120. Allergan's anticompetitive conduct has substantial intrastate effects in that, inter alia, retailers within each state were impaired in offering less expensive generic Restasis to end-payors inside each respective state. The impairment of competition from generic Restasis directly affects and disrupts commerce for end-payors within each state.

CLAIMS FOR RELIEF

COUNT I
Monopolization Under State Law For *Walker Process* Fraud

121. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

122. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed monopoly power in the market for cyclosporine ophthalmic emulsion. During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

123. From May 17, 2014 through at least the present day, Allergan has willfully, illegitimately, and unlawfully maintained its monopoly power in the cyclosporine ophthalmic emulsion market by obtaining patents by fraud and then enforcing those fraudulent patents against potential generic competitors to keep them from entering the market.

124. Allergan's monopoly power is not the result of its superior product or business acumen.

125. Allergan knowingly and intentionally asserted the invalid "second wave" patents in order to maintain its monopoly power. This was intended to, and in fact had the effect of, blocking and delaying market entry of generic cyclosporine ophthalmic emulsion.

126. Allergan, by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar), made misrepresentations of fact to the Patent and Trademark Office. These included:

a. Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Teat Test score in the first study of Allergan's Phase 3 trials compares to the relative efficacy for the…formulation discussed in Example 1E of Ding, tested in Phase 2 trials…This was clearly a very surprising and unexpected result."

b. Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "…the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the…formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result."

c. Figures 1-4 in Dr. Schiffman's declaration reported figured from the Sall paper but omitted all error bars and p-values. In truth, as the Court later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high. The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance.

d. Dr. Schiffman did not disclose to the PTO that he was comparing different Schirmer tear test scores—one without anesthesia in Phase 2 and one with anesthesia in Phase 3—in order to purportedly show a difference in efficacy. As the Court later found, only the Schirmer tear test results with anesthesia in Phase 3 significantly favored the 0.05%

cyclosporine formulation. "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation' was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper.

e. Dr. Schiffman did not disclose to the PTO that the method he chose to calculate the differences in efficacy "exaggerated the difference in the raw values between the two."

f. The calculations in Dr. Schiffman's table are misleading: (1) Dr. Schiffman used ratios of the degree of improvement, which tends to overstate the difference between the results; (2) Dr. Schiffman ignored the fact that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant; and (3) Dr. Schiffman only included data from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the second wave formulation.

g. Dr. Schiffman did not tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was "unexpected" as of the Restasis patent's priority date.

127. These representations were material. The PTAB examiner had repeatedly rejected Allergan's earlier applications as obvious *before* Allergan's misleading statements and omissions. The examiner had also previously dismissed Allergan's purported secondary considerations, including commercial success and unmet need. The PTAB's later decision, as well as this Court's later decision, support the materiality of these misrepresentations and omissions.

128. Allergan made these statements with intent to deceive the PTO. Allergan was motivated by its desire to maintain its monopoly power in the cyclosporine ophthalmic emulsion market beyond the May 2014 expiration of the Ding I and related patents. There is

no innocent explanation for presenting the information as it was presented in the misleading declaration and accompanying submissions; the only reasonable inference is that Allergan intended to deceive the PTO.

129. The PTO reasonably relied on Allergan's false and misleading statements in issuing the second wave patents. The examiner stated that the Schiffman declaration was deemed sufficient to overcome his earlier rejection based on Ding I because "Examiner is persuaded that, unexpectedly, the claimed formulation…demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy for the formulation disclosed in Ding I." The Examiner also explained that the declarations "illustrate that the claimed formulations…also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compare to the…formulation tested in Phase 2 and disclosed in Ding…"

130. But for Allergan's misrepresentations and omissions, the "second wave" patents would not have issued and there would have been no patent-based impediment to generic versions of cyclosporine ophthalmic emulsion entering the market from May 17, 2014 onwards.

131. Allergan wrongfully listed the "second wave" patents in the Orange Book and later asserted them against all would-be generic competitors.

132. But for Allergan's prosecution of its fraudulently obtained patents, generic cyclosporine ophthalmic emulsion would have been available as early as May 17, 2014, and in any case within the Class Period.

133. There is no valid procompetitive justification for Allergan's blatantly anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

134. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Kansas Stat. Ann. § 50-161 (b) et seq., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases in New Hampshire by members of the Class.

p. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law §340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

v. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

w. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

y. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

z. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

135. Plaintiff and members of the Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

136. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT II
Monopolization Under State Law For Allergan's Anticompetitive Scheme

137. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

138. As described above, from 1995 until the present (and with continuing effects hereafter), Allergan possessed monopoly power in the market for cyclosporine ophthalmic emulsion. During the relevant time period, no other manufacturer sold a competing version of any cyclosporine ophthalmic emulsion product in the United States.

139. From May 17, 2014 through at least the present day, Allergan has willfully, illegitimately, and unlawfully maintained its monopoly power in the cyclosporine ophthalmic

emulsion market by obtaining patents by fraud and then enforcing those fraudulent patents against potential generic competitors to keep them from entering the market.

140. Allergan's monopoly power is not the result of its superior product or business acumen.

141. Allergan knowingly and intentionally asserted the invalid "second wave" patents in order to maintain its monopoly power. This was intended to, and in fact had the effect of, blocking and delaying market entry of generic cyclosporine ophthalmic emulsion.

142. Allergan knowingly and intentionally engaged in an anticompetitive scheme in order to maintain its monopoly power, the components of which, separately and in conjunction, were designed to, and in fact did, block and delay entry of AB-rated generic versions of cyclosporine ophthalmic emulsion. This scheme included:

a. Prosecuting serial baseless patent applications and ultimately obtaining the second wave patents by fraud through misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;

b. Improperly listing the second wave patents in the Orange Book;

c. Wrongfully trying to enforce the second wave patents in multiple lawsuits.

d. Submitting serial baseless citizen petitions; and

e. Abusing the Patent Trial and Appeal Board's *inter partes* review process through an anticompetitive transfer of the second wave patents to the Saint Regis Mohawk Tribe.

143. Allergan knowingly and intentionally committed *Walker Process* fraud to induce the PTO to grant the "second wave" patents. Specifically, Allergan—after repeated denials of prior substantially similar serial applications over more than a 10-year period—submitted false sworn declarations in 2013, that Allergan characterized, by commission and

omission, as presenting new data that showed surprising results not anticipated by prior art (*i.e.*, Ding I), when in fact the data presented was neither new or surprising. Had Allergan made clear to the PTO examiner that the 2013 declarations statements and data were lifted from prior art known to Allergan for over 10 years, as Allergan's Duty of Disclosure, Candor, and Good Faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the "second wave" patents.

144. Allergan knew when it listed the "second wave" patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the second wave patents should not have been listed in the Orange Book. Allergan knew that listing the second wave patents in the Orange Book would force ANDA applicants to file paragraph IV certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, could trigger an automatic stay of any FDA final approval of any new paragraph IV-certified ANDA applicant's generic Restasis product for a period of up to 30 months.

145. Allergan knowingly and intentionally instituted multiple sham patent infringement actions against potential generic competitors that no reasonable pharmaceutical company in Allergan's position would realistically expect to win. Allergan intentionally and deceptively alleged the generic manufacturers' products infringed its "second wave" patents, knowing full well at the time that such patents were fraudulently obtained and were

otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew at the time those multiple sham suits were filed that there was no realistic likelihood a court would enforce the fraudulently-obtained and otherwise invalid "second wave" patents against a generic manufacturer. Allergan knew, therefore, that it had no reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed the sham lawsuits for the sole purpose of exploiting federal law to serve their anticompetitive ends.

146. Allergan knowingly and intentionally submitted multiple baseless citizen petitions to the FDA when no reasonable pharmaceutical manufacturer in Allergan's position would expect the FDA to grant the requested relief. The purpose and intent of these petitions was delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition.

147. In an effort to maintain their Restasis monopoly and avoid having their "second wave" patents invalidated by the PTAB, Allergan knowingly and intentionally transferred the "second wave" patents to the Tribe—a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands in New York. This scheme illustrates the lengths Allergan was willing to go to in order to avoid competition in the market for cyclosporine ophthalmic emulsion.

148. Allergan's anticompetitive conduct as alleged herein is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine.

149. There is no valid procompetitive business justification for Allergan's anticompetitive conduct, and to the extent Allergan offers one, it is pretextual and not

cognizable, and any procompetitive benefits of Allergan's conduct do not outweigh its anticompetitive harms.

150. By engaging in the foregoing conduct, Allergan has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Kansas Stat. Ann. § 50-161 (b) et seq., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases in New Hampshire by members of the Class.

p. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law §340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

v. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

w. R.I. Gen. Laws §§ 6-36-5 *et seq.,* with respect to purchases in Rhode Island by members of the Class.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

y. Tenn. Code Ann §§ 47-25-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

z. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

151. Plaintiff and members of the Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

152. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT III
Conspiracy in Restraint of Trade Under State Law

153. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

154. Defendant entered into a contract, with the Tribe in unreasonable restraint of trade.

155. Allergan's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the United States cyclosporine ophthalmic emulsion market and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for cyclosporine ophthalmic emulsion and raising and maintaining Restasis prices at supracompetitive levels throughout the United States.

156. As a result of their unlawful conspiracy, Allergan and the Tribe have effectively excluded competition from the cyclosporine ophthalmic emulsion market, allowing Allergan to unlawfully maintain its illegitimate monopoly. What is more, both Allergan and the Tribe have profited from their illegal contract.

157. There is no legitimate business justification for the anti-competitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the cyclosporine ophthalmic emulsion market, including the contract between Allergan and the Tribe. The anti-competitive effects of Allergan's and the Tribe's contract far outweigh any conceivable pro-competitive benefit or justification.

158. By engaging in the foregoing conduct, Defendant has intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Kansas Stat. Ann. § 50-161 (b) et seq., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

m. Mo. Rev. Stat. §§ 416.011, *et seq.*, with respect to purchase in Missouri by members of the Class.

n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

o. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases in New Hampshire by members of the Class.

p. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law §340 ("The Donnelly Act"), with respect to purchases in New York by members of the Class.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

v. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

w. R.I. Gen. Laws §§ 6-36-5 *et seq.*, with respect to purchases in Rhode Island by members of the Class.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

y. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

z. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

159. Plaintiff and members of the Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

160. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT IV
Conspiracy to Monopolize Under State Law

161. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

162. Allergan and the Tribe have conspired to allow Allergan to willfully maintain and unlawfully exercise monopoly power in the Restasis market through the anti-competitive contract with the specific intent to monopolize the Restasis market, and preventing competition in the market.

163. Allergan's contract in restraint of trade and its other anticompetitive acts were intentionally directed at the United States cyclosporine ophthalmic emulsion market and had a substantial and foreseeable effect on interstate commerce by interfering with potential generic competition for cyclosporine ophthalmic emulsion and raising and maintaining Restasis prices at supracompetitive levels throughout the United States.

164. As a result of their unlawful conspiracy, Allergan and the Tribe have effectively excluded competition from the cyclosporine ophthalmic emulsion market, allowing Allergan to unlawfully maintain its illegitimate monopoly. What is more, both Allergan and the Tribe have profited from their illegal contract.

165. There is no legitimate business justification for the anti-competitive actions of Allergan and the Tribe and the conduct through which Allergan maintained its monopoly in the market. The anti-competitive effects of Allergan's and the Tribe's agreement far outweigh any conceivable pro-competitive benefit or justification.

166. By engaging in the foregoing conduct, Defendant has intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.2 *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class, in that thousands of sales of Restasis took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendant's conduct.

o. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class.

p. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

r. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by members of the Class.

s. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

t. 10 L.P.R.A. § 251, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

u. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

v. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

w. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Restasis and AB-rated generic equivalents at Tennessee pharmacies.

x. Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

y. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class.

z. Wis. Stat. § 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Restasis at Wisconsin pharmacies.

167. Plaintiff and members of the Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia,

and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

168. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT V
Unjust Enrichment Under State Law
(Fifty States & District of Columbia, Except Ohio and Indiana)

169. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

170. Defendant has benefited from substantially increased profits as a result of its unlawful conduct.

171. Defendant's financial benefits resulting from its unlawful and inequitable conduct are traceable to overpayments for Restasis by Plaintiff and members of the Class.

172. Plaintiff and the Class have conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

173. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Restasis, as those intermediaries are not liable and would not compensate Plaintiff or the Class for damages caused by the unlawful conduct of Defendant.

174. The economic benefit of overcharges and unlawful monopoly profits derived by Defendant through charging supracompetitive and artificially inflated prices for Restasis is a direct and proximate result of Defendant's unlawful practices.

175. The financial benefits derived by Defendant rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendant.

176. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendant to be permitted to retain any of the overcharges for Restasis derived from Defendant's unfair and unconscionable method, acts, and trade practices alleged in this Complaint.

177. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds that it derived from its anticompetitive scheme.

178. A constructive trust should be imposed upon all unlawful or inequitable sums received Defendant traceable to Plaintiff and the Class.

179. Plaintiff and the Class have no adequate remedy at law.

COUNT VI
Unfair and Deceptive Trade Practices Under State Law

180. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

181. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic version of Restasis and forced to pay higher prices.

182. There was and is a gross disparity between the price that Plaintiff and the Class members paid and for the brand Restasis product and the value received, given that a much cheaper substitute generic product should have been available sooner and in greater quantity, and prices for brand Restasis should have been much lower, but for Defendant's unlawful conduct.

183. By engaging in the foregoing conduct, Defendant has engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by members of the Class.

b. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases in Arizona by members of the Class.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases in the District of Columbia.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

f. Kan. Stat. §§ 50-623, *et seq.*, with respect to the purchases in Kansas by members of the Class.

g. Idaho Code §§ 48-601, *et seq.*, with respect to the purchases in Idaho by members of the Class.

h. 815 ILCS §§ 505/1, et seq., with respect to the purchases in Illinois by members of the Class.

i. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases in Maine by members of the Class.

j. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class.

k. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases in Michigan by members of the Class.

l. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

m. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by members of the Class.

n. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska by members of the Class.

o. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in Nevada by members of the Class.

p. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class.

q. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases in New Mexico by members of the Class.

r. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by members of the Class.

s. N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases in North Carolina by members of the Class.

t. Or. Rev. Stat. §§ 646.605, *et seq.,* with respect to purchases in Oregon by members of the Class.

u. 73 Pa. Con. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases in Pennsylvania by members of the Class.

v. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island by members of the Class

w. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases in South Dakota by members of the Class.

x. Tenn. Code §§ 47-18-101, *et seq.,* with respect to purchases in Tennessee by members of the Class.

y. Utah Code §§13-11-1, *et seq.*, with respect to purchases in Utah by member of the Class.

z. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases in Virginia by members of the Class.

aa. Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases in Vermont by member of the Class.

bb. West Virginia Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by members of the Class.

184. Plaintiff and members of the Class have been injured in their business or property by reason of Allergan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic products, and (2) paying higher prices for products than they would have paid in the absence of Allergan's conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

185. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Allergan's violations of the aforementioned statutes.

COUNT VII
Injunctive and Declaratory Relief Under Section 16 of The Clayton Act for Allergan's Violations of Sections 1 and 2 of The Sherman Act

186. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

187. Plaintiff's allegations described herein and in claims One through Seven comprise a violation of Sections 1 and 2 of the Sherman Act, as well as state laws *supra*.

188. Plaintiff and the members of the Class face an ongoing threat of injury for the Defendant's unlawful conduct, which is ongoing. Moreover, Plaintiff and the members of the Class are threatened with injury, and are being injured, as result of prior unlawful conduct by the Defendant.

189. Plaintiff and the members of the proposed Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201, hereby seek a declaratory judgment that Defendant's conduct in

seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

190. Plaintiff and the members of the proposed Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Allergan's unlawful conduct, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, demands judgment against Defendant for the following relief:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff representative of the Indirect Purchaser Class;

b. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses

c. Enter joint and several judgments against Defendant in favor of Plaintiff and the Class;

d. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

e. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

f. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendant, and as the Court deems just.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demands a jury trial as to all issues so triable.

Respectfully Submitted,

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